Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) for the Treatment of People Living With HIV: 24-Month Analyses by Age, Race, Sex, Adherence and Late Diagnosis in a Multi-Country Cohort Study

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To access a plain language summary of the 24-month BICSTaR study results and to access the supplemental data for this poster, please scan the QR code

Introduction

B/F/TAF is a guideline-recommended single-tablet regimen for the treatment of HIV-1 infection that can contribute to long-term treatment success in people living with HIV[1]

BICSTaR is a large, ongoing, multi-country, prospective, observational study that has enrolled 2,380 ARV treatment-naïve (TN) and treatment-experienced (TE) people in Europe (France, Germany, Ireland, Italy, the Netherlands, Spain, UK), Canada, Israel, Japan, Taiwan, South Korea and Singapore

Methods

In this planned analysis with a data cutoff of August 4, 2021, **pooled 24-month effectiveness and safety** data are presented for people receiving B/F/TAF in routine clinical care from France, Germany, Ireland, Italy, the Netherlands, Spain, UK, Canada and Israel

We describe data both in the overall population and in key groups related to sex, age, race, treatment adherence level, late diagnosis and prior use of TDF (for weight only)*

*With exception of individuals with a late diagnosis, key group analyses were restricted to the TE participants due to the small numbers in the TN group

Study Design

BICSTaR

N = 838

HIV-1 infection
TN or TE
≥ 18 years of age

Cutoff date for analysis: August 4, 2021

Baseline — 12 months: primary endpoint[2] — 24 months

B/F/TAF once daily

Pooled data from 838 participants with baseline and Month 24 data or who had discontinued B/F/TAF and/or study prior to the cutoff date

24-month study outcomes included:

- HIV-1 RNA < 50 c/mL (Missing = Excluded and Discontinuation = Failure analyses)
- Treatment persistence (% of participants reaching Month 24 and still on B/F/TAF)
- Drug-related AEs
- Weight changes (people with weight and BMI available at baseline and 24 months)

Conclusions

- B/F/TAF showed high effectiveness and persistence after 24 months in a cohort of people living with HIV in routine clinical care
- Together with clinical trial data, these real-world data continue to support the broad use of B/F/TAF in both treatment-naïve and treatment-experienced individuals

Effectiveness: % HIV-1 RNA < 50 c/mL at 24 Months – Overall Population

Missing = Excluded analysis (n = 628)

- (104/107) 95% CI: 92, 99 — **97%** of TN participants
- (497/521) 95% CI: 93, 97 — **95%** of TE participants

Discontinuation = Failure analysis (n = 732)

- (104/117) 95% CI: 82, 94 — **89%** of TN participants
- (497/615) 95% CI: 77, 84 — **81%** of TE participants

Effectiveness: % HIV-1 RNA < 50 c/mL at 24 Months – Key Groups

By late diagnosis (< 350 cells/μL) (TN)

- 96% (95% CI: 85, 100) with late diagnosis (44/46)
- 98% (95% CI: 90, 100) without late diagnosis (54/55)
- *P* = 0.656, Fisher exact

By sex (TE)

- 97% (95% CI: 89, 100) of females (62/64)
- 95% (95% CI: 93, 97) of males (435/457)
- *P* = 0.755, Fisher exact

By age (TE)

- 95% (95% CI: 92, 97) of people < 50 years (246/259)
- 96% (95% CI: 93, 98) of people ≥ 50 years (251/262)
- *P* = 0.655, chi square

By race (TE)

- 94% (95% CI: 84, 99) of Black race (48/51)
- 96% (95% CI: 93, 97) of people of other races* (449/470)
- *P* = 0.721, Fisher exact

*Majority of people in this group were White

By adherence (TE)

- 93% (95% CI: 81, 99) of people with < 95% adherence (40/43)
- 96% (95% CI: 93, 98) of people with ≥ 95% adherence (262/274)
- *P* = 0.654, Fisher exact

Change from Baseline in CD4 Cell Count at 24 Months – Overall Population

Median (Q1, Q3)	Baseline	TN (N = 94)	24 months	Median change*	Baseline	TE (N = 424)	24 months	Median change*
CD4 cell count, cells/μL	**424** (184, 542)	→	**661** (480, 865)	**+228**	**657** (428, 870)	→	**704** (520, 926)	**+48**
				P < 0.001 sign test				*P* < 0.001 sign test

*Calculated as changes from baseline to 24 months for each individual participant

Baseline Characteristics

TN (N = 135)		TE (N = 703)
13% / 87%	Female / Male	14% / 86%
39 (30, 51)	Age,* years	49 (39, 56)
26% / 4%	≥ 50 years / ≥ 65 years	48% / 7%
70† (63, 81)	Weight,* kg	76 (66, 87)
23‡ (21, 26)	BMI,* kg/m²	25§ (22, 28)
77%	White	82%
11%	Black	10%
4%	Asian	3%
53%	Any comorbidity	73%
18%	Neuropsychiatric condition	29%
8%	Hyperlipidemia	20%
7%	Hypertension	19%
1%	HIV-1 RNA < 50 c/mL	92%
424 (184, 542)	CD4 count,* cells/μL	657 (428, 870)
0.31 (0.19, 0.59)	CD4/CD8 ratio*	0.84 (0.60, 1.20)
41%	Late presenters: CD4 < 350 cells/μL and/or ≥ 1 AIDS-defining event at baseline	N/A
27%	Late presenters: CD4 < 200 cells/μL and/or ≥ 1 AIDS-defining event at baseline	N/A
N/A	Immediate prior ART regimen¶: - NNRTI / PI / INSTI -	19% / 15% / 68%
N/A	Immediate prior NRTI - TDF / TAF / ABC -	34% / 48% / 14%

*Median (Q1, Q3); †n = 121; ‡n = 116; §n = 595; ¶An individual may be included in > 1 drug class

Persistence

Participants reaching 24 months and still receiving B/F/TAF

- 86% — of overall population (720/838)
- 89% — of all TN participants (120/135)
- 85% — of all TE participants (600/703)

118 (14%) of participants discontinued B/F/TAF through 24 months for any reason

Key Safety Data Through 24 Months

Overall population (N = 838)	By sex (TE): Female (n = 96)	By sex (TE): Male (n = 607)	By age (TE): < 50 y (n = 369)	By age (TE): ≥ 50 y (n = 334)
128 (15%)* with DRAE(s)	15 (16%)	89 (15%)	61 (17%)	43 (13%)
	P = 0.805, chi square¶		*P* = 0.173, chi square¶	
2† (< 1%) serious DRAEs	0	2 (< 1%)	1 (< 1%)	1 (< 1%)
	P = 1.000, Fisher exact¶		*P* = 1.000, Fisher exact¶	
62 (7%)‡ discontinued B/F/TAF due to DRAEs§	9 (9%)	45 (7%)	31 (8%)	23 (7%)

*TN: 18% (24/135), TE: 15% (104/703); †Both in the TE group; ‡TN: 6% (8/135), TE: 8% (54/703); §Most commonly weight increase (3%) and depression (1%); ¶Chi square and Fisher exact tests for the difference between groups: the null hypothesis was that there were equal proportions in the two groups

Weight (kg) – Overall and Key Groups

Median (Q1, Q3)	Baseline	TN (N = 75)*	24 months	Median change†	Baseline	TE (N = 376)*	24 months	Median change†
Overall	**69** (63, 80)	→	**75** (68, 84)	**+4.3¶** (0, 9)	**76** (67, 87)	→	**77** (69, 89)	**+1.2¶** (-1.0, 4.5)
By baseline CD4	**68** (63, 72)	TN < 350 cells/μL (N = 33)* →	**73** (70, 83)	**+6.6¶** (1.4, 10.0)	**70** (62, 80)	TN ≥ 350 cells/μL (N = 39)* →	**79** (67, 84)	**+4.0¶** (-0.3, 8.0)
By sex	**65** (59, 74)	TE Female (N = 49)* →	**65** (58, 78)	**+0.5** (-1.6, 3.0)	**78** (69, 88)	TE Male (N = 327)* →	**79** (70, 90)	**+1.3¶** (-1.0, 4.8)
								P = 0.150 Wilcoxon test§
By age	**76** (66, 86)	TE < 50 y (N = 185)* →	**77** (68, 88)	**+1.5¶** (-0.9, 4.7)	**77** (68, 87)	TE ≥ 50 y (N = 191)* →	**78** (70, 89)	**+1.0¶** (-1.0, 4.3)
								P = 0.324 Wilcoxon test§
By race	**72** (65, 85)	TE Black (N = 36)* →	**74** (66, 86)	**+0.9** (-1.0, 4.3)	**77** (67, 87)	TE Other‡ (N = 340)* →	**78** (69, 89)	**+1.2¶** (-1.0, 4.5)
By prior TDF	**77** (67, 87)	TE No TDF (N = 237)* →	**78** (69, 90)	**+1.0¶** (-1.0, 4.5)	**74** (67, 86)	TE Prior TDF (N = 137)* →	**77** (68, 88)	**+2.0¶** (0.0, 4.3)

*Population with weight and BMI data available at baseline and 24 months; †Calculated as changes from baseline to 24 months for each individual participant; ‡People of other races, of which the majority were White; §Non-parametric test null hypothesis was that there were equal median changes in the two subgroups; ¶*P* < 0.05 for change from baseline in group using the sign test (null hypothesis that there was zero change from baseline)

References
1. Panel on Antiretroviral Guidelines for Adults and Adolescents. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf (accessed Jul 22, 2022);
2. Mallolas J, et al. EACS 2021, Poster PE2/57

Abbreviations
AE, adverse event; ART, antiretroviral treatment; ARV, antiretroviral; BICSTaR, Bictegravir Single Tablet Regimen; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; DRAE, drug-related adverse event; INSTI, integrase strand transfer inhibitor; N/A, non-applicable; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; TDF, tenofovir disoproxil fumarate; TE, treatment-experienced; TN, treatment-naïve

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